

REMARKS

Claims 80 – 82, 84 – 87 and 96 – 103 are pending. No claims are hereby added, cancelled or amended.

I. Rejections under Section 103 – Claims 80 – 82, 84 – 87 and 96 - 103

In the Official Action, all remaining claims are now rejected as obvious over U.S Patent No. 5,957,861, issued to Combs, et al. in view of Scheulke, et al.(US 5,775,742) This rejection is respectfully traversed for the reasons set forth below..

A. Rejections of Claims 80 – 82, 84, 85 and 96 – 101

Applicants previously stated:

“the lead impedance measuring circuitry in Scheulke employs a lead impedance measurement technique quite different from that of Combs’861. The pulses generated to measure impedance are generated by the high voltage output circuitry of Scheulke rather than the pacing pulse generation circuitry as used by Combs, et al. The arrangement for measuring impedance in Scheulke is optimized to measure lead impedance while the impedance measurement arrangement in Combs ‘861 is optimized to measured tissue impedance. Addition of the lead integrity measurement system of Scheulke to Combs thus would result in a device having two separate impedance measurement mechanisms. Absent some recognition that the same impedance measurements may be simultaneously usefully employed to measure both lead tissue impedance and lead integrity, it is respectfully asserted that combining the Scheulke and Combs’861 references does not render the inventions as claimed in any of the remaining claims obvious. Both Combs ‘861 and Scheulke lack this same essential teaching.”

In response to the above statements, the Examiner states:

However, Schuelke et al. discloses "the lead integrity check may also be undertaken during delivery of a pacing pulse" (col 3, lines 22-23). Therefore, the system does not require the separate measurements, but can be used at the same time. In addition, "impedance trend suggesting an impending failure that may be monitored more closely or may result in replacement of the lead or re-positioning of the lead electrode" (col. 3, lines 303-35). Therefore, Schuelke et al. discloses the monitoring of the impedance data taken during a delivery pulse, as well as the trending to monitor the impending failure of a lead.

It is respectfully noted that the Examiner's comments do not actually contradict any of the Applicant's above statements, and the proposed combination still does not produce a device meeting the claims, even if the measurement pulses in Scheulke are taken during delivery, of the pacing pulses. The Examiner's argument is respectfully asserted to be clearly incorrect for the following three reasons.

1. Measurement during pacing pulses in Scheulke does not teach measurement using the same mechanism as in Combs.

Even if the measurements of impedance as in Scheulke are done during delivery of the pacing pulses, they are still done using the high voltage circuitry. Addition of the measurement system of Scheulke to Combs still produces a device with two fundamentally different impedance measuring systems, precisely as previously stated by Applicants.

Applicants' previous argument on this point was intended to address the Examiner's contention that combining g the two references would produce a device in which fluid content and lead integrity are measured using the same mechanism.

Neither reference suggests this conclusion. The Examiner's reply does not actually respond to Applicants' argument.

Withdrawal of the rejections of claims 80 – 82, 84, 85 and 96 – 101 is respectfully requested for this reason.

2. Measurement during pacing pulses in Scheulke does not even teach measurement at the same time as in Combs.

The measurement of impedances as in Combs does not occur during the pacing pulses. It is done using the pacing pulse circuitry, but not during delivery of the pacing pulses. The impedance measuring drive signal applied to the tissue differs from the pacing pulses and thus cannot be done during delivery of the pacing pulses. If lead impedance measurement is done during the pacing pulses as in Scheulke as now argued by the Examiner, it cannot be incorporated into Combs and have the result of using the same mechanism to both measure lead integrity and fluid content as required by the claims. The teaching in Scheulke now relied upon by the Examiner thus teaches directly away from the claimed invention rather than making it obvious.

Withdrawal of the rejections of claims 80 – 82, 84, 85 and 96 – 101 is respectfully requested for this reason as well.

3. Measurement during pacing pulses as in Scheulke is irrelevant to the invention as claimed

The claims do not require measurement during the delivery of pacing pulses. The claims require that measurement occurs: (a) responsive to a cardiac event and (b) at a predetermined interval therefrom. Even if delivery of the pacing pulse is understood to be a "cardiac event", delivery during cannot be reasonably understood to be delivery at an interval therefrom. Thus, even if all impedance measurements were taken during the pacing pulses as apparently proposed by the Examiner, the claims would still not be met.

Withdrawal of the rejections of claims 80 – 82, 84, 85 and 96 – 101 is respectfully requested for this reason as well.

B. Rejections of Claims 86, 87, 102 and 103

Applicants previously set forth two reasons these claims were improperly rejected.

1. Cross-checking of measured impedances between two electrodes

Applicants previously stated:

"These claims are rejected based upon the assertion that Scheulke teaches cross-checking of measured impedances between two electrodes by measuring impedance using a third electrode. However, the portions of Scheulke discussed in conjunction with this rejection deal with individual impedance measurements of individual lead impedances performed using three electrodes. A single measurement of each relevant lead impedance is made using a different selected set of three electrodes. The cross checking function as claimed simply is not present. Claims 86, 87, 102 and 103 (as renumbered) are this respectfully asserted to be patentable over the cited references for this reason, regardless of the patentability of the other claims."

The Final Office Action does not respond to or dispute the above statements.

Withdrawal of the rejections of claims 86, 87, 102 and 103 is again respectfully requested for this reason.

2. Set of impedances indicative of tissue fluid content

Applicants also previously stated:

"Further, these claims all require that the impedance measurements which are cross checked are a set of impedances indicative of tissue fluid content. This aspect of

the claimed is similarly undisclosed in Scheulke. The impedance measurements of Scheulke are of lead impedance and are not cross-checked as a set for any purpose whatsoever."

The Final Office Action does not respond to or dispute the above statements.

Withdrawal of the rejections of claims 86, 87, 102 and 103 is respectfully requested for this reason as well.

C. Rejections of Claims 81 and 97

Applicants previously set forth two reasons these claims were improperly rejected.

1. Impedances indicative of fluid content valid or invalid as a result of the lead integrity measurement

Applicants previously stated:

"These claims require declaring the set of measured impedances indicative of fluid content valid or invalid as a result of the lead integrity measurement. Neither combs'861 nor Scheulke discloses or suggests this aspect of the claimed invention."

The Final Office Action does not respond to or dispute the above statements.

Withdrawal of the rejections of claims 81 and 97 is again respectfully requested for this reason as well.

2. First Office Action does not even mention this aspect of the claimed invention

Applicants previously stated:

"Further, because the Office Action does not even mention this aspect of the claimed invention it is respectfully asserted that the rejection under Section 103 is inadequate as a matter of law for not clearly setting forth an argument as to why the combination of the cited references makes this aspect of the invention obvious."

The Final Office Action does not respond to or dispute the above statement.

Withdrawal of the rejections of claims 81 and 97 is again respectfully requested for this reason as well.

D. Rejections of Claims 87 and 103

Applicants previously set forth two reasons these claims were improperly rejected.

1. Declaring the set of measured impedances indicative of fluid content valid or invalid as a result of the cross-check measurement

Applicants previously stated:

"These claims require declaring the set of measured impedances indicative of fluid content valid or invalid as a result of the cross-check measurement. Neither combs'861 nor Scheulke discloses or suggests this aspect of the claimed invention. Claims 87 and 103 (as renumbered) are this respectfully asserted to be independently patentable over the cited references for this reason, regardless of the patentability of the other claims."

The Final Office Action does not respond to or dispute the above statement.

Withdrawal of the rejections of claims 87 and 103 is again respectfully requested for this reason as well.

2. The First Office Action does not even mention this aspect of the claimed invention

Applicants previously stated:

"Further, because the Office Action does not even mention this aspect of the claimed invention, it is respectfully asserted that the rejection under Section 103 is inadequate as a matter of law for not clearly setting forth an argument as to why the combination of the cited references makes this aspect of the invention obvious."

The Final Office Action does not respond to or dispute the above statement.

Withdrawal of the rejections of claims 87 and 103 is respectfully requested for this reason as well.

E. Rejections of Claims 84, 85, 86, 99, 100 and 101 (as renumbered)

Applicants previously set forth two reasons these claims were improperly rejected.

1. Comparing the set of measured impedances indicative of fluid content to prior measured impedances and declaring the data set valid or invalid as a result of this comparison

Applicants previously stated:

"These claims all require comparing the set of measured impedances indicative of fluid content to prior measured impedances and declaring the data set valid or invalid as a result of this comparison. Neither combs'861 nor Scheulke discloses or suggests this aspect of the claimed invention."

The Final Office Action does not respond to or dispute the above statement.

Withdrawal of the rejections of claims 84, 85, 86, 99, 100 and 101 is again respectfully requested for this reason as well.

2. The First Office Action does not even mention this aspect of the claimed invention

Applicants previously stated:

"Further, because the Office Action does not even mention this aspect of the claimed invention, it is respectfully asserted that the rejection under Section 103 is inadequate as a matter of law for not clearly setting forth an argument as to why the combination of the cited references makes this aspect of the invention obvious."

The Final Office Action does not respond to or dispute the above statement.

Withdrawal of the rejections of claims 84, 85, 86, 99, 100 and 101 is again respectfully requested for this reason as well.

It is respectfully requested that any new ground of rejection be in the form of a non-final rejection, as no claims have been amended in a manner that would allow for a second final rejection based upon new references.

Conclusion

All remaining claims are respectfully asserted to be allowable over the Combs '949 patent in view of the Scheulke patent. Reconsideration of the rejections of the remaining claims is respectfully requested.

Finally, if there are any formal matters remaining after this response, the Examiner is requested to telephone the undersigned attorney to attend to these matters.

Should any issues remain outstanding, the Examiner is urged to telephone the undersigned to expedite prosecution. The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 13-2546.

Respectfully submitted,

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